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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,080	08/30/2001	Carlo Effenhauser	RDID01056US	7687
41577	7590	10/14/2005	EXAMINER	
WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP BANK ONE TOWER/CENTER 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137			SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,080	EFFENHAUSER ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-17 and 20-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17 and 20-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8-22-05</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 24-27 and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Yuzhakov et al (2002/0168290 A1).

Yuzhakov et al disclose a lancing system and further disclose a lancing unit configured to couple to a drive unit, the lancet unit including a detection zone configured to analyze the body fluid; a capillary structure having a lancing tip configured to create an incision in the skin, the lancing tip defining a capillary groove for drawing the body fluid from the incision to the detection zone via capillary action, wherein the capillary groove opens longitudinally along the outside of the lancing tip to permit collection of the body fluid along the length of the lancing tip; the drive unit is coupled to the lancing unit; the lancing unit including a holding area in which a portion of the capillary structure is arranged; the holding area has a distal end form where the lancing tip extends and a top surface; the capillary groove opens along the top surface of the holding area; the lancing unit includes a plate capping the holding area; the plate covers a portion of the capillary groove; the plate defines a window over the detection zone; the capillary structure includes a solid needle with a capillary groove defined therein; the detection

Art Unit: 3736

zone includes an optical detector for analyzing body fluid; the detection zone includes an electrochemical detector for analyzing the body fluid; the lancing tip has a distal end that initially contacts the skin during lancing; and the capillary groove further opens at the distal end of the lancing tip. See Paragraphs 0074, 0082, 0085, 0095, 0099, and 0113.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yuzhakov et al (2002/0168290 A1) as applied to claim 24 above, and further in view of Ramel (5,540,709).

Yuzhakov et al, as discussed above, disclose a lancing system, but fail to disclose a pair of needles joined together.

Ramel discloses a lancing system and further discloses a pair of needles joined together. See Figures 17A and 17B.

Since both Yuzhakov et al and Ramel disclose lancing systems, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the lancing device of Yuzhakov et al to include two needles joined together, as per the

Art Unit: 3736

teachings of Ramel, since it would provide an alternate means of lancing the skin to acquire a blood sample.

5. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yuzhakov et al (2002/0168290 A1) as applied to claim 24 above, and further in view of Eriksen (2,359,550).

Yuzhakov et al, as discussed above, disclose a lancing system, but fail to disclose a stranded wire with the capillary groove formed between adjacent wires.

Eriksen discloses a vaccinator and further discloses a stranded wire with the capillary groove formed between adjacent wires. See Figure 1.

Since both Yuzhakov et al and Eriksen disclose means for penetrating the skin, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the lancing device of Yuzhakov et al to include a stranded wire, as per the teachings of Eriksen, since it would provide an alternate means of penetrating the skin.

6. Claims 13-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuzhakov et al (2002/0168290 A1) in view of Garcia et al (4,637,403).

Yuzhakov et al, as discussed above, disclose a lancing system and further disclose a drive unit; a disposable lancing unit which has a holding area that is removably positioned in the holder; an elongate capillary structure, wherein a proximal end of the capillary structure comprises at least one capillary channel for transporting a body fluid connected to the holding area; a distal end of the capillary structure suitable for piercing the skin, wherein the capillary structure is located outside the skin in a first position and

Art Unit: 3736

inserted into the skin in a second position; the capillary channel is open to the outside in an area which comprises at least part of the longitudinal extension of the capillary structure extending beyond the distal end; the entire length of the capillary structure is open to the outside; the holding area has a detection zone for detecting at least one analyte, the detection zone being arranged to use capillary action to take up the body fluid; the capillary structure and the holding area are integrally connected together; the capillary structure that is open to the outside has a channel shape; the channel shape is a V-shaped cross-section; the length of the capillary structure is in the range of 0.3-3.0 mm and the cross-section of the capillary structure is in the range of 0.03-0.8 mm; and the holding area and the capillary structure are made of silicon. See Paragraphs 0074, 0082, 0085, 0095, 0099, and 0113.

Yuzhakov et al however fail to disclose the drive unit moves the lancing device such that after the lancing device reaches the second position, the lancing device is moved back into a collecting position; and the drive unit moves the lancing unit in such a manner that it remains in the second position for a time interval and subsequently, the lancing unit is moved into a position in which the distal end of the capillary structure is outside the skin.

Garcia et al disclose the drive unit moves the lancing device such that after the lancing device reaches the second position, the lancing device is moved back into a collecting position; and the drive unit moves the lancing unit in such a manner that it remains in the second position for a time interval and subsequently, the lancing unit is moved into a

position in which the distal end of the capillary structure is outside the skin. See Column 9, lines 41-66; and Column 12, lines 15-21.

Since both Yuzhakov et al and Garcia et al disclose drive units for lancets, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Yuzhakov et al to include the specifics of the drive unit of Garcia et al, since it would provide a means of moving the lancing unit to acquire a fluid sample.

Response to Arguments

7. Applicant's arguments with respect to claims 13-17 and 20-23 have been considered but are moot in view of the new ground(s) of rejection.

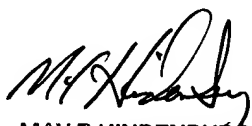
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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